L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact on small entities. Because no current activity is prohibited by this final rule, the compliance cost to firms is zero. Because no increase in the health risks faced by consumers will result from this final rule, total costs are also zero. Potential benefits include wider use of this substance because of reduced uncertainty concerning its GRAS status, and any resources saved by eliminating the need to prepare further petitions to affirm the GRAS status of this substance for this use. The agency certifies, therefore, that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VI. References

The following references have been placed on display in the Dockets Management (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Gurr, M. I., and A. T. James, *Lipid Biochemistry: An Introduction*, John Wiley and Sons, Inc., New York, 1975.

2. Memorandum dated September 6, 1988, from M. Dinovi to J. Ziyad, ''GRP 8G0344—Parexel Int. Corp. (PI) for Gattefossé, SA. Glyceryl Palmitostearate.''

3. Park, Y. K., and E. A. Yetley ''Trend Changes in Use and Current Intakes of Tropical Oils in The United States'' *American Journal of Clinical Nutrition* 51:738–748, 1990.

4. Select Committee on GRAS Substances. ''Evaluation of the Health Aspects of Glycerin and Glycerides as Food Ingredients'' (SCOGS–30) PB–254 536, 1975.

5. Food and Agriculture Organization of the United Nations, ''Toxicological Evaluation of Some Food Additives Including Anticaking Agents, Antimicrobials, Antioxidants, Emulsifiers and Thickening Agents.'' FAO Nutrition Meetings Report Series No. 53A, Rome, 1974.

List of Subjects in 21 CFR Part 184

Food additives, Food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 184 is amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

2. New § 184.1329 is added to subpart B to read as follows:

§ 184.1329 Glyceryl palmitostearate.

(a) Glyceryl palmitostearate is a mixture of mono-, di-, and triglyceryl esters of palmitic and stearic acids made from glycerin, palmitic acid, and stearic acid.

(b) The ingredient meets the following specifications:

(1) The substance is a mixture of mono-, di-, and triglycerides of palmitic acid and stearic acid.

(2) Heavy metals (as lead): Not more than 10 parts per million.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a formulation aid, as defined in § 170.3(o)(14) of this chapter.

(2) The ingredient is used in excipient formulations for use in tablets at levels not to exceed good manufacturing practice.

Dated: November 16, 1995.

Janice F. Oliver,

Deputy Director for Systems and Support, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–30125 Filed 12–11–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 510, 520, and 522

Animal Drugs, Feeds, and Related Products; Diphenylhydantoin Sodium Capsules, et al.

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to remove those portions of the regulations that reflect approval of one new animal drug application (NADA) held by Parke-Davis, Division of Warner-Lambert Co., three held by Akorn, Inc., and one held by Veterinary Research and Development, Inc. All of the sponsors submitted written requests that the agency withdraw approval of the NADA's. In a notice published elsewhere in this issue of the Federal Register, FDA is withdrawing approval of the NADA's.

EFFECTIVE DATE: December 22, 1995.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0159.

SUPPLEMENTARY INFORMATION: In a notice published elsewhere in this issue of the Federal Register, FDA is withdrawing approval of the following NADA's:

NADA No.	Drug name	Sponsor name and address
6–032	Diphenylhydantoin sodium capsules	Parke-Davis, Division of Warner-Lambert Co., 201 Tabor Rd., Morris Plains, NJ 07950
12–444	Sterile prednisolone suspension	Akorn, Inc., 100 Akorn Dr., Abita Springs, LA 70420
94–978	Phenylbutazone injection	Do.
110–046	Dexamethasone injection	Do.
140–904	Copper disodium edetate injection	Veterinary Research and Development, Inc., P.O. Box 1299, Truckee, CA 95734

The sponsors requested withdrawal of approval of the NADA's because the drug products are no longer being marketed. This final rule removes 21 CFR 520.704, 522.514, and 522.1880, and amends 21 CFR 522.540 and 522.1720 to reflect the withdrawal of approval of these NADA's.

In addition, 21 CFR 510.600(c) is amended to remove the entries for the three sponsors from the list of approved drug sponsors because they no longer hold any approved NADA's.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520 and 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entries for ''Akorn, Inc.,'' ''Parke-Davis, Division of Warner-Lambert Co.,'' and ''Veterinary Research and Development, Inc.'' and in the table in paragraph (c)(2) by removing the entries for ''000071,'' ''017478,'' and ''057428.''

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 520.704 [Removed]

4. Section 520.704 *Diphenylhydantoin sodium capsules* is removed.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

5. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 522.514 [Removed]

6. Section 522.514 *Copper disodium edetate injection* is removed.

§ 522.540 [Amended]

7. Section 522.540 *Dexamethasone injection* is amended by removing paragraph (d)(2)(ii) and by redesignating paragraph (d)(2)(iii) as paragraph (d)(2)(ii).

§ 522.1720 [Amended]

8. Section 522.1720 *Phenylbutazone injection* is amended in paragraph (b)(1) by removing the phrase ''000031, 017220, 015579, and 017478'' and adding in its place ''000031, 017220, and 015579''.

§ 522.1880 [Removed]

9. Section 522.1880 *Sterile prednisolone suspension* is removed.

Dated: December 4, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–30123 Filed 12–11–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Monensin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Animal Health, Division of Eli Lilly and Co. The supplemental NADA provides for use of an approved monensin Type A medicated article to make a revised formulation of a monensin Type C medicated feed/free-choice mineral granule fed to pasture cattle for increased rate of weight gain.

EFFECTIVE DATE: December 12, 1995.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2701.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, filed supplemental NADA 95–735, which provides for use of 80 grams(g) per pound monensin Type A articles to make a monensin Type C medicated feed/free-choice mineral granule containing 1,620 g per ton monensin. The Type C feed/free-choice mineral granules are fed to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) for increased rate of weight gain. The supplemental NADA provides for a revised formulation Type C free-choice mineral granule. The revised formulation does not affect the safety or effectiveness data and information upon which the application is approved. The supplemental NADA is approved as of December 12, 1995, and the regulations are amended in 21 CFR 558.355 by adding new paragraph (f)(3)(x) to reflect the approval.

Use of a Type A medicated article to make a free-choice Type C medicated feed/ mineral granule requires an approved Form FDA 1900 as in 21 CFR 510.455.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval does not qualify for marketing exclusivity because the supplement does not contain reports of new clinical or field investigations or new human food safety studies (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant.

A freedom of information summary for this approval is not required because it involves approval of a revised formulation which does not affect the basis of approval of the product. A summary of the data and information submitted to support the original approval may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(iii) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows: